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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,395	04/27/2007	Ronald W. Wood	176/61672(1246)	1398

26774 7590 07/10/2009

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EXAMINER	
QIAN, CELINE X	
ART UNIT	PAPER NUMBER
1636	
MAIL DATE	DELIVERY MODE
07/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,395	WOOD ET AL.	
	Examiner	Art Unit	
	CELINE X. QIAN	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending in the application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, drawn to a method of diagnosing a pelvic pain disorder or determining predisposition of an individual to conditions associated with pelvic pain disorders by measuring a level of CGRP or PACAP or both in a patient sample and compared to healthy individual.

Group II, claim(s) 18-29, drawn to a method of treating a pelvic pain disorder in patient by providing a CGRP antagonist.

Group III, claim 30, drawn to a method of characterizing response to treatment for a pelvic pain disorder comprising measuring a level of CGRP or PACAP, or both in a sample, treating the patient with a CGRP or PACAP antagonist, and repeating the measurement after treatment to determine whether treatment is effective.

Group IV, claims 31-35, 38 and 39, drawn to a transgenic non-human mammal comprising a DNA construct expressed in bladder sensory neurons which expresses a neuropeptide, being CGRP.

Group V, claims 31-36, 38 and 39, drawn to a transgenic non-human mammal comprising a DNA construct expressed in bladder sensory neurons which expresses a neuropeptide, being CGRP, and further comprising a second DNA construct comprising a promoter specific for urothelial tissues and a DNA molecule encoding the rtTA protein.

Group VI, claims 31-39, drawn to a transgenic non-human mammal comprising a DNA construct expressed in bladder sensory neurons which expresses a neuropeptide, being CGRP, and further comprising a second DNA construct comprising a promoter specific for urothelial tissues and a DNA molecule encoding the rtTA protein, and further comprising a third DNA construct comprising an inducible promoter operably linked to a coding sequence for peptidyl glycine amidating monooxygenase.

Group VII, claims 31-35, 38 and 39, drawn to a transgenic non-human mammal comprising a DNA construct expressed in bladder sensory neurons which expresses a neuropeptide, being PACAP.

Group VIII, claims 31-36, 38 and 39, drawn to a transgenic non-human mammal comprising a DNA construct expressed in bladder sensory neurons which expresses a neuropeptide, being PACAP, and further comprising a second DNA construct comprising a promoter specific for urothelial tissues and a DNA molecule encoding the rtTA protein.

Group IX, claims 31-39, drawn to a transgenic non-human mammal comprising a DNA construct expressed in bladder sensory neurons which expresses a neuropeptide, being PACAP, and further comprising a second DNA construct comprising a promoter specific for urothelial tissues and a DNA molecule encoding the rtTA protein, and further comprising a third DNA construct comprising an inducible promoter operably linked to a coding sequence for peptidyl glycine amidating monooxygenase.

Group X, claims 40 and 41, drawn to a recombinant CGRP polypeptide that is amidated at its carboxyl terminus.

Group XI, claims 40 and 42, drawn to a recombinant PACAP polypeptide that is amidated at its carboxyl terminus.

Group XII, claims 43-47, drawn to a recombinant DNA construct encoding the recombinant polypeptide of CGRP.

Group XIII, claims 43-47, drawn to a recombinant DNA construct encoding the recombinant polypeptide of PACAP.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature. The inventions listed as Groups I-XIII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The special technical feature of Group I is the relationship between CGRP, PACAP and pelvic pain disorder, which is not shared by the remaining groups. The special technical feature of Group II is CRGP antagonist, which is not shared by other groups. The special technical feature of Group III is the expression of CGRP, PACAP and its usefulness in determining treatment of pelvic pain disorder, which is not shared by other groups. The special technical feature of Group IV is a transgenic non-

human mammal expressing CGRP, which is not shared by other groups. The special technical feature of Group V is a transgenic non-human mammal expressing CGRP and rtTA protein, which is not shared by other groups. The special technical feature of Group VI is a transgenic non-human mammal expressing CGRP, rtTA protein and peptidyl glycine amidating monooxygenase, which is not shared by other groups. The special technical feature of Group VII is a transgenic non-human mammal expressing PACAP, which is not shared by other groups. The special technical feature of Group VIII is a transgenic non-human mammal expressing PACAP and rtTA protein, which is not shared by other groups. The special technical feature of Group IX is a transgenic non-human mammal expressing PACAP, rtTA protein and peptidyl glycine amidating monooxygenase, which is not shared by other groups. The special technical feature of Group X is a recombinant CGRP protein, which is not shared by other groups. The special technical feature of Group XI is a recombinant PACAP protein, which is not shared by other groups. The special technical feature of Group XII is a recombinant DNA construct encoding CGRP, which is not shared by other groups. The special technical feature of Group XIII is a recombinant DNA construct encoding PACAP, which is not shared by other groups. Therefore, the unity of invention does not exit between the claims of Groups I-XIII.

The claims of Group I is directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

The method of diagnosing or determining predisposition of conditions associated with pelvic pain disorder select from the disorder listed in claims 8 and 17.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

The method of diagnosing or determining predisposition of conditions associated with pelvic pain disorder select from the disorder listed in claims 8 and 17.

The following claim(s) are generic: Claims 1-7, 9-16.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the diseases listed in claims 8 and 17 ranging from interstitial cystitis, Crohn's disease, ulcerative colitis...etc, which has different symptoms and causes. As such, they do not share same or corresponding

special technical features. Consequently, the special technical feature between different pelvic pain disorders and the expression of CGRP and PACAP is also different.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636